Montana Cancer Clinical Trials Advisory Council

Consensus Guidelines for ERISA-Regulated and Self-Funded Plan Coverage of Routine Patient Care Costs Associated with Cancer Clinical Trials

Introduction

With the passage of HB 615, the 2011 Legislature directed the Office of the Commissioner of Securities and Insurance (CSI) to study issues related to the equitable treatment by insurers for cancer patients seeking to participate in cancer clinical trials. As commissioner, I sought input from an advisory council of medical providers, insurers, employers, patients and patient- advocates.

The council reached a consensus on a definition of routine care which is contained in Appendix A. The group recommended the Children, Families, Health and Human Services Interim Committee request and support legislation incorporating this definition into Montana law and that all health insurance plans over which the state has jurisdiction be prohibited from denying coverage for routine care during clinical trials. Federal law will require coverage of trials by self-funded plans on January 1, 2014.

For self-funded employer health plans, over which CSI has limited jurisdiction, the council recommended a voluntary commitment form to provide the framework for third party payer coverage for patient care costs for those enrolled in clinical trials within the scope of the individual's benefit plan. Coverage for patients in the interim period between now and 2014 could mean longer lives for many Montana cancer patients.

The Cancer Clinical Trials Advisory Council believes that this agreement, along with the codification of their consensus routine care definition in Montana statute for health insurance plans to use as a guide in providing coverage for patients' routine care, will increase access to clinical trials for cancer patients in Montana. If oncologists are able to enroll more patients in clinical trials, they will be able to advance treatment for the long term, and provide the best possible care for their current patients.

The adoption of the Advisory Council's consensus routine care definition will make routine care distinct from experimental or investigational treatments so that coverage for routine care for patients enrolled in clinical trials in any phase the same as that provided patients not in a trial. The adopted definition would decrease patient and provider confusion about policy language and insurer practice during clinical trials. The new definition also would assure patients and providers more consistency for trial coverage determinations.

Cancer clinical trials provide outcomes data necessary to assess medical practice and build on evidence based, value driven health care. Scientific oversight helps to focus rational decision making within these studies. Montana healthcare payers could

benefit from the advancement in science, avoidance of useless treatment and continuous quality improvement in cancer care clinical research provides. The goal of this agreement is to increase participation in select cancer-related clinical trials by making payment for services provided within the context of clinical trials predictable. The Montana Cancer Clinical Trials Advisory Council agreed that health plans that the health plans that the state does not have jurisdiction over should volunteer to provide coverage for the routine care costs of patient participation in approved clinical trials.

Appendix A

COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

‘‘(a) COVERAGE.—

‘‘(1) IN GENERAL.—If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer—

‘‘(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

‘‘(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

‘‘(C) may not discriminate against the individual on the basis of the individual’s participation in such trial.

‘‘(2) ROUTINE PATIENT COSTS.—

‘‘(A) INCLUSION.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine
patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

‘‘(B) EXCLUSION.—For purposes of paragraph (1)(B), routine patient costs does not include—

‘‘(i) the investigational item, device, or service, itself;

‘‘(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient;

‘‘(iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis; or

“(iv) items or services customarily provided by a clinical trial sponsor.

‘‘(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

‘‘(4) USE OF OUT-OF-NETWORK.—Notwithstanding paragraph (3), paragraph (1) shall apply to a qualified individual participating in an approved clinical trial that is conducted outside the State in which the qualified individual resides.

‘‘(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term ‘qualified individual’ means an individual who is a participant or beneficiary in a health plan or with coverage described in subsection (a)(1) and who meets the following conditions:

‘‘(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer.

‘‘(2) Either—

‘‘(A) the referring health care professional is a participating health care provider and

has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

'(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

''(c) LIMITATIONS ON COVERAGE.—This section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan's (or coverage's) health care provider network unless out-of network
benefits are otherwise provided under the plan (or coverage).

''(d) APPROVED CLINICAL TRIAL DEFINED.—

''(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer that is not designed exclusively to test toxicity or disease pathophysiology, that has therapeutic intent, and is described in any of the following subparagraphs:

''(A) FEDERALLY FUNDED TRIALS.—The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

''(i) The National Institutes of Health.
''(ii) The Centers for Disease Control and Prevention.
''(iii) The Agency for Health Care Research and Quality.
''(iv) The Centers for Medicare & Medicaid Services.
''(v) cooperative group or center of any of the entities described in clauses (i)through (iv) or the Department of Defense or the Department of Veterans Affairs.
''(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.
''(vii) Any of the following if the conditions described in paragraph (2) are met:
''(I) The Department of Veterans Affairs.
''(II) The Department of Defense.
''(III) The Department of Energy.

''(B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

''(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

''(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

''(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

''(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

Conclusion

If coverage of routine care for cancer clinical trials in Montana continues with the inconsistency there is now, many Montana cancer patients will never get the opportunity to receive the best possible treatment and opportunity for a longer life. Without access to cancer clinical trials, there are no answers to significant current questions regarding treatment for patients whose cancer has failed to respond to standard therapy or for which no effective standard therapy exists.

While federal law will require coverage of clinical trials by self-funded plans on January 1, 2014, many cancer patients will be denied access to a clinical trial before then without this routine care coverage agreement. This agreement will not only decrease confusion for providers and patients by creating consistency in routine care coverage, but the advancement in science and quality improvement in cancer clinical research would save insurers money in the long term by avoiding less effective treatment and discovering treatment that makes patients healthier and requires less continuous treatment.

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This document represents an agreement by the undersigned to provide Montana's cancer patients with access to high-quality, peer-reviewed cancer clinical trials, with appropriate coverage and payment for routine patient care services by their health care plans. The purpose of this agreement is to assure patient access to cancer clinical trials in a manner that is both fiscally responsible and medically appropriate.

The undersigned agree to adhere to the principles as defined in this document in developing policies for coverage of the routine patient care costs associated with cancer clinical trials:

_____	_____
(Signature)	**(Signature)**
_____	_____
(Print/Type Name)	**(Print/Type Name)**
_____	_____
(Title)	**(Title)**
_____	_____
(Date)	**(Date)**

Representing:

_____

(Organization/Institution)